

ASWBPL-EAST: FROZEN BLOOD INITIATIVE 2001-2002



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Assurance Program
Bolling AFB Washington DC



FROZEN BLOOD PROGRAM

- IMMEDIATE BLOOD SUPPLY IN PREPOSITIONED LOCATIONS
- INITIAL STAGES: CONTINGENCY OPS/WAR UNTIL RBCs ARRIVE
- PACOM/EUCOM/CONUS
- BPDs/NAVY SHIPS/MTFs/ASWBPL
 - ~ 55K UNITS: BPDs/SHIPS/MTFs
 - ~ 10K: ASWBPLs: SUPPLEMENT
- CURRENTLY ~ 68% EXP/NT HIV-p24

FROZEN BLOOD PROGRAM CONT'

- DoD IG #D-201-059/FEB 01:
 - CURRENT INVENTORY OF FRZs SHOULD BE REPLACED
- POST 9/11: Op NOBLE EAGLE:
 - TREMENDOUS DONOR RESPONSE
- TASKING: ASD(HA) VIA ASBPO:
 - EXPEDITE BLOOD FREEZING PROGRAM AT ASWBPL-EAST

A photograph of the ASWBPL East building at McGuire AFB, NJ. The building is a large, dark-colored industrial structure with a corrugated metal roof. A white van is parked on the left side of the building, and a dark SUV is parked on the right side. In the foreground, there is a black sign with white text that reads "1705 ASWBPL EAST Armed Services Whole Blood Processing Laboratory". The sky is overcast, and there are some bare trees in the background.

1705

ASWBPL EAST
Armed Services Whole
Blood Processing
Laboratory

ARMED SERVICES WHOLE BLOOD
PROCESSING LABORATORY
McGUIRE AFB NJ



HAEMONETICS ACP215

- FDA 510K CLEARED:
SUBSTANTIALLY EQUIVALENT TO H115
(LEGALLY MARKETING ESTABLISHED DEVICE)
- CLOSED SYSTEM (STERILE CONNECT)
- POST-THAW LIFE: 14 DAYS (AS-3)
- ~ H115 TECHNOLOGY
- 800 ML CPDA-1 PVC BAGS
- 10 YEAR EXPIRATION

ASWBPL-EAST FRZ INITIATIVE CONT'

- 10 ACP215s: LATE SEP 2001
- DAVIS-M
- BLOOD MOBILE: WRAMC
- FDA VALIDATION: SEP –
- AF ACADEMY
- 9-MAN 2 LIVE ASWBPL CREW TEAM



**CAMP MEMORIAL BLOOD CENTER
FORT KNOX, KENTUCKY**



ASWBPL-EAST FRZ INITIATIVE CONT'

- FDA: DIVIDED COOPERATIVE
MANUFACTURE ARRANGEMENT
- JOINT MANUFACTURE
- NAVY/GREAT LAKES/CMDR ALLEN:
800 ML CPDA-1 WEEKLY
- LABEL: ALL MANUFACTURERS

QUALITY CONTROL

- DONOR HGB/HCT < 15.3/46%
- WB WEIGHT < 450 GRAMS
(SG~1.053)
- PACKED RBCS ~ 75% HCT
- FROZEN BLOOD ~ 60% HCT
- DEGLYCED PROD~ 50-55% HCT

QUALITY CONTROL CONT'

- % RECOVERY > 80%
- HGB DOSAGE: NBRL/HAEMONETICS
- STERILITY
- FINAL PROD RESIDUAL GLYCEROL < 1G%
- WASTE SUPRNAT FREE HGB < 200MG%
-CHEMSTRIP/ "3" COLOR COMPARATOR
- REFRACTION VALUE < 40
- FINAL PROD SUPRNAT K⁺ < 1.5 MeQ/L

GLYCEROLIZATION









4622705

4622705

OKC





4622827
20-34-21



RED BLOOD CELLS

4622827

Rh POSITIVE

VOLUME R DONOR

CODE 4R1247M
LOT M01B27065

PL 148⁺ Product

4622827
20-34-21

GLYCEROLIZATION



- WARM RBC: 5/20 MIN
- SURFACE 20 -30 C
- ACP 215: 10-15 MIN
- GLYCEROL EXT: 60/40
- PRODUCT LABEL: DMA
- 2 CRYOVIALS/PPT/BOX





GLYCEROLIZATION

- LONG TERM STORAGE/-65C/10 YEARS FROM COLLECTION



DEGLYCEROLIZATION










DEGLYCEROLIZATION

- THAW: ~35 MIN
 - SURFACE 30-34 C
- ACP 215: ~ 60 MIN
- LABEL (PEND' FDA APPROVAL)



FINDINGS: QA/REGULATORY

- HEAT/HUMID: DEGLYING KITS
- AUTO ERROR CODES: INVALID PROD
- WASTE BACKUP: BOWL
- DEGLYCED RBCS IN BOWL: LOW REC
- AS-3 APPROVAL
- HIGH HGB/HCT- LOW RECOVERY
- PLASMA THAWER-FDA 510K CLEARANCE PENDING
- STORAGE TEMP -65C VS -80C
- HAEMONETICS: ON SITE JAN 2002

A man wearing glasses and a white lab coat is standing in a laboratory. He is holding a small bottle and pouring its contents into a multi-well plate. In the background, there is a white machine with a digital display, a sink with a faucet, and a green container with a pump. The wall is tiled with white and grey tiles.

BLOOD WARMING/THAWING: FDA SPECIAL 510k CLEARANCE



SOFTWARE UPGRADE: JAN 2002









WHERE ARE WE AT?

- PRIOR APPROVAL SUPPLEMENT (PAS) SUBMISSION TO FDA
- TOTAL FROZEN ~ 400 UNITS
- DEGLYCED ~ 200/50 VALIDATION
- FROZEN ON SHELF ~ 175 UNITS
- LABEL: RED BLOOD CELLS FROZEN (CLOSED): PENDING
- VALIDATED 2 SOPS/WKSHTS
- NBRL/DR VALERI/WRAIR/DR LIPPERT
- THROUGHPUT RATE

WHERE ARE WE GOING?

- AUTHORIZATION: MANUFACTURE FROZEN/DEGLYCED RBCs(ASWBPL)
- ON-SITE INSPECTION (FDA)
- HAEMONETICS: FDA APPROVAL TO DEGLYCE H115 FRZS ON ACP215

WHERE ARE WE GOING?

CONT'

- FDA APPROVAL FOR OTHER COAGULANTS/ADDITIVE SOLNS
- ASWBPL WEST
- WRIGHT PATTERSON/LACKLAND VALIDATING COLLECTION SOP
- BETTER PLASTIC BAG: WRAIR
- > 10 YEAR EXPIRATION?

CONCLUSION

- ASWBPL EAST/WEST WILL PLAY SIGNIFICANT ROLE IN DoD/ASBPO FROZEN BLOOD REPLACEMENT PLAN



FORCE PROTECTION/AFOSI: McGUIRE AFB DSN 650-5555

